



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 26, 2000

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 65402-1 / VigorOx Liquid Sanitizer
DP Barcode: D266967
Case No: 031420

To: Marshall Swindell, PM 33
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Emily Mitchell, Team Leader *Emily Mitchell 10/26/00*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Applicant: FMC Corporation

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Peroxyacetic Acid	5.1
Hydrogen Peroxide	21.7
<u>Other Ingredient(s):</u>	<u>73.2</u>
Total:	100.0%

The supplemental data/information hand delivered by Keller and Heckman is acceptable to support the claims for *Escherichia coli*, *Salmonella typhimurium*, using 75 ppm solution of Vigorox 5% when exposed for 30 seconds. The product was also effective against *Listeria monocytogenes* using 100 ppm solution of Vigorox 5% when exposed for 30 seconds.

PM: Make sure the label claims are the same as the accepted supplemental efficacy data.



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October 5, 2000

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 65402-1 / VigorOx Liquid Sanitizer
DP Barcode: D266967
Case No: 031420

To: Marshall Swindell, PM 33
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, PM 34
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Ian Blackwell

Through: Emily Mitchell, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Emily Mitchell 10/19/00

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: FMC Corporation

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Peroxyacetic Acid	5.1
Hydrogen Peroxide	21.7
<u>Other Ingredient(s):</u>	<u>73.2</u>
Total:	100.0%

BACKGROUND: FMC Corporation has submitted two product efficacy studies in support of their product "VigoroX Liquid Sanitizer". The purpose of these studies is:

1. To reduce the concentration (lower limit) of peroxyacetic acid needed for institutional industrial sanitizing of previously cleaned, non-porous surfaces.
2. To add to the label that this product is an effective sanitizer against *Salmonella typhimurium* and *Listeria monocytogenes*.

RECOMMENDATIONS: PSB findings are:

1. MRID Number 451300-1: "Food Contact Sanitizer Test on VigoroX Liquid Sanitizer and Disinfectant, 5% Peroxyacetic acid." By Daniel L. Prince, Ph.D. Gibraltar Laboratories, Inc. GBL Study # GR 1573. Study Completion Date 4/7/2000.

VigoroX 5%, when diluted to a concentration of 85 ppm in 400 ppm AOAC Hard Water, killed 99.999% of *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) when exposed for 30 and 60 seconds at 25 °C. This supports FMC Corporations desire for labeling stating that sanitization of surfaces contaminated with *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538) may be carried out using a 85 ppm solution of VigoroX 5%.

The report lists a reported "log reduction" for the two species tested, but does not give the bacterial count for the control (non-test material-treated) or treated bacteria. This is a major flaw in this study/report. **This study is currently unacceptable.** This study cannot be accepted until this raw data giving the treated and untreated bacterial counts is reported.

2. MRID Number 451300-02: "Food Contact Sanitizer Test On VigoroX Liquid Sanitizer 5%" GR 1532. by Daniel L. Prince, Ph.D. Gibraltar Laboratories, Inc. GBL Study # 1532. Study Completion Date 12/16/99.

VigoroX Liquid Sanitizer 5% killed 99.999% of *E. coli* (ATCC #35150) and *Salmonella typhimurium* (ATCC #14028) within 30 seconds at concentrations of 50 ppm and 100 ppm when diluted into 400 ppm AOAC hard water with a 5% organic soil load. VigoroX Liquid Sanitizer 5% killed 99.999% of *Listeria monocytogenes* (ATCC #984) in 30 seconds at a concentration of 100 ppm when diluted into 400 ppm AOAC hard water with a 5% organic soil load. VigoroX Liquid Sanitizer 5% **did not** kill 99.999% of *Listeria monocytogenes* within 30 seconds at 50 ppm

This study had a report in that the report claimed that *E. coli*, *Salmonella typhimurium* and *Listeria monocytogenes* (against a 50 ppm concentration of test material) were conducted against VigoroX Liquid Sanitizer **15%**, not 5%. An E-Mail from the Daniel L. Prince of Gibraltar Labs (see attached) clarified this matter and informed us that this study only tested VigoroX Liquid Sanitizer 5%, and that there is no VigoroX Liquid Sanitizer 15%.

After the problems with the test material identification were resolved, it then became apparent that this report does not give any information on a positive control. The report lists a reported "log reduction" for the three species tested, but does not give the bacterial count for the control (non-test material-treated) or treated bacteria. This is a major flaw in this study/report. **This study is currently unacceptable.** This study cannot be accepted until this raw data giving the treated and untreated bacterial counts is reported.

LABELING:

1. Under the section titled "Sanitizing Non-Porous Food Contact Surfaces, #6: *Listeria monocytogenes* should be italicized.